Treatment of traumatic corneal abrasions: a three-arm, prospective, randomized study

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Treatment of Traumatic Corneal Abrasions: A Three-Arm, Prospective, Randomized Study

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Key Words
Traumatic abrasion · Reepithelialization · Treatment options · Corneal abrasion area

Abstract
Purpose: To compare three different treatment modalities for traumatic corneal abrasions. ***Methods:*** We conducted a prospective, randomized, masked, three-arm clinical study of patients presenting with superficial corneal foreign bodies. Treatment modalities were: (1) pressure patching with ofloxacin ointment (patch group, PG, n = 18), (2) therapeutic contact lens with ofloxacin eye drops (contact lens group, CLG, n = 20) and (3) ofloxacin ointment alone (ointment group, OG, n = 28). Primary outcome measure was the difference of the mean corneal abrasion area between the three groups at 3 different time points (baseline, day 1 and day 7). ***Results:*** A total of 66 patients were included in the study over a period of 2 years. Mean initial corneal abrasion area was 3.6 ± 3.4 mm^2 in the PG, 4.2 ± 4.0 mm^2 in the CLG and 3.7 ± 3.1 mm^2 in the OG (p = 0.875). Differences in corneal abrasion area at any time point were not statistically significant (abrasion area decrease from presentation to day 1 was 3.4 ± 3.3 mm^2 in the PG, 4.1 ± 4.0 mm^2 in the CLG and 3.5 ± 3.1 mm^2 in the OG, p = 0.789). The epithelium was healed in all patients at day 7. ***Conclusions:*** Treating traumatic corneal abrasions by pressure patching, a bandage contact lens or ointment alone was equal in reducing the abrasion area or reducing pain. According to our results the treatment of choice for traumatic abrasions may be adapted to the needs and preferences of the patient.

Introduction

Traumatic corneal abrasion leads to significant morbidity and medical leave. The incidence of these often work-related eye injuries has been reported as high as 15 per 1,000 people per year of which 87% were traumatic corneal abrasions [1]. Similarly, an audit performed in 2003 showed that traumatic corneal abrasions due to external foreign bodies are among the most common conditions treated in an emergency eye department [2].

General treatment strategies for corneal epithelial defects are either application of topical antibiotics and

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short-term occlusion with a pressure patch, topical antibiotic ointment as a stand-alone therapy or temporary use of bandage contact lenses. Pressure patching can lead to disadvantages such as loss of binocular vision, discomfort from the patch itself and reduced corneal oxygenation [3]. The advantages of an ophthalmic ointment in preference to antibiotic eye drops include a longer contact time of the applied substance on the ocular surface and increased lubrication, which shields the epithelial defect from constant friction by the eyelids. An extensive Cochrane systematic review by Turner and Rabiu [4] was conducted to determine the effects of eye patching for treating corneal abrasions. In their review of studies [5–15], they found no evidence for the use of eye patches for simple corneal abrasions as they did not improve day 1 postinjury healing rates nor reduce pain, and were associated with discomfort [4]. However, they observed that many of the studies did not declare a proper randomization process and had a high number of dropouts. The application of a soft therapeutic contact lens has been considered in various studies [16–21], among the first being reports from outcomes of treatment of corneal abrasions following excimer laser photorefractive keratectomy [16, 21]. Contact lenses have been associated with a greater relief of pain and photophobia as well as vision increase compared to 'traditional' methods of treatment.

The purpose of our study was to compare three different treatment modalities for corneal abrasions secondary to removal of foreign bodies (i.e. pressure patching, antibiotic ointment alone and use of bandage contact lenses) with respect to the following: (1) reduction in corneal abrasion area after distinct time points, (2) pain relief, (3) duration of medical leave, (4) residual corneal opacity and (5) use of analgesics in a prospective randomized manner.

Materials and Methods

This single-center, prospective, masked and randomized study was conducted at the Department of Ophthalmology, University Hospital of Zurich, Switzerland from October 2008 to April 2010. The study was approved by the local ethics committee and adhered to the tenets of the Declaration of Helsinki. After informed consent had been obtained, all adults (≥18 years) diagnosed and treated for a superficial corneal foreign body at the Department of Ophthalmology were enrolled in the study. Exclusion criteria were the following: infectious keratitis, advanced trauma with stromal loss, corneal abnormalities including epithelial, stromal or endothelial dystrophies, chemical trauma, limbal stem cell deficiency, use of chronic topical eye medication, collagen vascular disease and children (patients under the age of 16). The topical anesthetic employed was oxybuprocaine (Oxybuprocaine 0.4% SDU Faure; Laboratoires Théa, Clermont-Ferrand, France). After removal of the corneal foreign body with a 25-gauge needle (Terumo® needle 25G × 5/8 inch; Terumo Medical Products, Tokyo, Japan) and a diamond burr (Alcon Grieshaber AG, Schaffhausen, Switzerland) by two ophthalmologists (P.B.K. and M.M.) using the exact same technique, the patients were randomly assigned to one of the following therapeutic modalities:

(1) pressure patch with ofloxacin ointment (Floxal® Augensalbe 3mg/g; Bausch and Lomb, Switzerland) (patch group, PG);

(2) contact lens (PureVision®, Bausch and Lomb) with non-preserved ofloxacin eye drops 4 times a day (Floxal® UD Augentropfen, Bausch and Lomb) (contact lens group, CLG);

(3) ofloxacin ointment 4 times a day (ointment group, OG).

Allocation to a treatment modality was conducted by a study nurse using numbered closed envelopes, randomized prior to the study start using www.randomization.com.

Patients in the PG received a double-firm pressure patch with a folded and an unfolded oval gauze taped over the injured eye after application of ofloxacin eye ointment. The patch was removed by the study nurse 30 min prior to ophthalmic examination at the follow-up visit. In the CLG, a therapeutic contact lens was inserted and the patients instructed to use ofloxacin eye drops 4 times a day. The bandage contact lens was removed by the study nurse 30 min prior to ophthalmic examination. Participants of the OG were instructed to apply ofloxacin ointment 4 times a day. The treating ophthalmologists were masked as best as possible to the different treatment groups. None of the patients received topical cycloplegics.

The treatment was continued until complete corneal abrasion area reduction (complete reepithelialization or epithelial regeneration line) could be observed. The follow-up was daily until complete corneal abrasion area reduction was seen and always 7 days after initial presentation.

The primary outcome measure was the reduction in corneal abrasion area (mm^2) from the time of the removal of the foreign body to 24 h and 1 week later (day 7). Documentation of the corneal abrasion area was performed by photography (magnification ×10) using a digital anterior segment camera (Zeiss FF 450 plus; Carl Zeiss GmbH, Oberkochen, Germany). The corneal abrasion area was documented shortly after corneal foreign body removal (<30 min) and at each follow-up visit. Assessment of corneal abrasion area in mm^2 was done by processing the digital photographs with a measuring tool (Synedra View® version 2.1.4.15; Synedra Information Technologies, Innsbruck, Austria) by two different ophthalmologists (M.M. and R.K.).

An important secondary outcome measure was the amount of pain assessed by using the Wong-Baker FACES Pain Rating Scale [22] at different time points. The grading scales used were first described by Wong and Baker, assessing pain in children. It may also successfully be used in visually impaired adults [23]. A recent review [24] analyzed the validity and reliability of different pain measures including our employed scale and stated that for the assessment of simple changes in pain intensity it was satisfactory. However, due to the large number of pain assessment tools there is a great diversity in dimensions and no international standard for pain assessment. We therefore decided to define a difference of 2 scores in the Wong-Baker FACES Pain Rating Scale as being clinically relevant. Patients graded the amount of pain at the initial presentation, 3 h after removal of the corneal foreign body and

after 24 h. For statistical analysis, the 6 different faces were allocated to the numbers 0, 2, 4, 6, 8 and 10. Pain relief was the difference between the pain score at presentation and the pain score after 3 and after 24 h, respectively. Further secondary outcome measures included the duration of medical leave, the presence of residual corneal opacities (yes/no) and the use of oral analgesics. This information together with past medical and ocular history were obtained by using a standardized questionnaire at initial presentation and at subsequent follow-up visits at days 1 and 7.

Safety data assessed included visual acuity (Snellen), the amount of conjunctival injection graded from 1 to 4 with a conjunctival injection score [25] and the documentation of serious adverse events (such as microbial keratitis). For calculation visual acuity scores were converted from Snellen to logMAR scale.

Statistical Analysis

Analysis was performed with SPSS version 18.0 (IBM, Chicago, Ill., USA). The sample size calculation was performed with nQuery Advisor® 7.0 (Statistical Solutions Ltd., Cork, Ireland) using one-way analysis of variance (equal n's) with a significance level (α) of 0.050 and a power of 0.8. Sample size calculation was performed for the primary outcome. With a power of 0.8 and a p value of 0.05 the sample size was calculated to be approximately 17 patients per group. We allowed for a loss to follow-up of 1 patient per group, thus a minimum of 18 patients were recruited for each group. Due to the lack of data on corneal abrasion reduction differences, a target difference of 2.0 mm^2/24 h – being considered clinically relevant by the authors – was defined.

Descriptive statistics with continuous variables are shown as mean ± standard deviation. Relative frequencies for discrete variables were computed. For normally distributed variables, a one-way ANOVA was applied in order to investigate differences between the means of continuous variables (i.e. corneal abrasion area reduction and pain relief). Post hoc analysis was performed with the Scheffé test. Alternatively, the nonparametric Kruskal-Wallis test was used. Differences between corneal abrasion area and pain score at day 0 and day 1/day 7 were calculated. The 95% confidence interval (95% CI) for the difference was computed with a paired t test. The differences of the mean corneal abrasion area reduction and mean decrease of pain score between the treatment groups were assessed with the one-way ANOVA or Kruskal-Wallis test. In order to investigate associations between two discrete variables, the χ^2 test was applied. The level of significance was set at 0.05.

Results

A total of 66 patients with work-related corneal foreign bodies were included in the study over a period of 2 years. None of the subjects included was identified as having a wooden or vegetable material foreign body. Of the total, 18 subjects were randomly assigned to pressure patch with ofloxacin ointment (PG), 20 subjects to contact lens with nonpreserved ofloxacin eye drops 4 times a day (CLG) and 28 subjects to ofloxacin ointment 4 times a day (OG). Three patients (4.5%; 1 PG, 2 OG) did not show up for the 1st follow-up visit (day 1) and were excluded from further analysis. The dropout rate at the 2nd follow-up visit (after 7 days) was 38% (n = 25). The dropouts were evenly distributed between the three groups (p = 0.678). The average age was 31.5 ± 11.9 years and all patients were male. All three groups were equally comparable regarding demographics and time to presentation (table 1).

Table 1. Baseline and demographic information

	PG	CLG	OG	p value
Subjects (n)	18	20	28	
Age	28.7±12.9	29.7±11.8	34.3±11.1	0.217
Gender	all male	all male	all male	
Time to presentation, h	27.0±32.8	25.2±35.4	39.5±38.7	0.117
Initial corneal abrasion area, mm^2	3.6±3.4	4.2±4.0	3.7±3.1	0.875
Initial pain score	4.8±1.7	4.8±2.2	3.9±1.5	0.243

Comparison of the groups was not statistically significant in any baseline or demographic finding (p values).

The data of the primary and secondary outcome measures with their corresponding p values of the analysis are shown in table 2. There was no statistically significant difference in primary outcome measure (corneal abrasion reduction) or in secondary outcome measures between the treatment groups. The abrasion area decreased from presentation to day 1 by 3.4 ± 3.3 mm^2 in the PG, 4.1 ± 4.0 mm^2 in the CLG and 3.5 ± 3.1 mm^2 in the OG (p = 0.789). The epithelium was healed in all patients at day 7. Despite a notable range in abrasion areas among our study patients, the statistical distribution of the intra- and intergroup sizes was homogenous. The 95% CI of the different abrasion areas in mm^2 was 2.0213–5.3532 for the PG, 2.2992–6.0418 for the CLG and 2.4467–4.9251 for the OG.

Since all included patients displayed complete corneal abrasion area reduction (complete reepithelialization or epithelial regeneration line) either after day 1 or day 2 (n = 3), the abrasion area measurements at day 7 were redundant.

Analysis of the results of pain relief at 3 h showed that the PG achieved a statistically significant level of pain relief (mean 1.2, 95% CI 0.2–2.1), while patients in the CLG and the OG remained without a statistically significant decrease in pain (mean 0.8, 95% CI –1.0 to 2.5 and mean –0.6, 95% CI –1.9 to 0.7, respectively). However, there was no statistically significant difference when the pain relief between the three groups was compared (Kruskal-Wallis test, p = 0.152).

Table 2. Primary and secondary outcome measure

		PG	CLG	OG	p value
Primary outcome measure					
Corneal abrasion	initial abrasion area	3.6±3.4	4.2±4.0	3.7±3.1	0.875
reduction, mm^2	area reduction at day 1	3.4±3.3	4.1±4.0	3.5±3.1	0.789
Secondary outcome measure					
Pain score	initial	4.8±1.7	4.8±2.2	3.9±1.5	0.243
	after 3 h	3.7±2.4	4.1±3.3	4.5±3.3	0.694
	after 24 h	0.8±1.6	0.9±1.3	1.7±2.7	0.227
Medical leave, days		2.0±1.6	1.5±2.1	1.9±2.2	0.553
Residual corneal opacities (%)		72	82	78	0.933
Use of analgesics (n)		3	2	7	0.316

The table shows data of the corneal abrasion area as mean mm^2 ± standard deviation at initial presentation and the area reduction after 24 h. The secondary outcome measure was assessed using the Wong-Baker FACES Pain Rating Scale. Comparison of the groups was not statistically significant in any outcome measure (p values).

The pain score after 24 h was 0.8 ± 1.6 in the PG, 0.9 ± 1.3 in the CLG and 1.7 ± 2.7 in the OG (one-way ANOVA, p = 0.227) corresponding to a pain relief of 4.1 ± 2.0 (95% CI 3.0–5.1) in the PG, 4.0 ± 2.4 (95% CI 2.8–5.1) in the CLG and 2.2 ± 3.0 (95% CI 0.9–3.4) in the OG 24 h after the therapeutic intervention (Kruskal-Wallis test, p = 0.04). However, the application of post hoc analysis was unable to indicate differing groups.

Oral analgesics were taken by 3 patients in the PG, 2 patients in CLG and 7 in the OG. Although a greater proportion of patients used analgesics in the OG, this finding was not statistically significant (χ^2 test, p = 0.316).

At day 7 the number of patients showing a residual corneal opacity was comparable between the three treatment groups (72% in the PG, 82% in the CLG and 78% in the OG, p = 0.933).

Best-corrected Snellen visual acuity at baseline was 0.9 ± 0.2 in the PG, 1.0 ± 0.2 in the CLG and 1.1 ± 0.3 in the OG. Assessment of visual acuity after 1 week showed an average of 1.1 ± 0.2 in the PG, 1.1 ± 0.2 in the CLG and 1.1 ± 0.2 in the OG (Kruskal-Wallis, p = 0.265). There was no statistically significant difference between the treatment groups regarding conjunctival injection at baseline (χ^2 test, p = 0.312) or day 1 (Kruskal-Wallis test, p = 0.660). The mean change in conjunctival injection after therapy assessed at day 1 was 0.7 ± 0.9 in the PG, 0.4 ± 1.2 in the CLG and 0.4 ± 1.2 in the OG (Kruskal-Wallis, p = 0.660). An increase of either 1 or 2 scores [25] in conjunctival injection was noted in 1 patient in the PG, in 4 patients in the CLG and in 7 patients in the OG (χ^2 test, p = 0.712). Assessment of conjunctival injection after 1 week revealed only 1 patient in the CLG with a grade 1 injection; all other subjects showed grade 0. No severe adverse events such as infectious keratitis occurred. One patient suffered a second corneal foreign body in the same eye at the 1-week follow-up examination. He was retreated and excluded from the analysis.

Discussion

Our study was able to show for the first time in a prospective, randomized, masked fashion that there is no statistically or clinically significant difference regarding the therapeutic value of the commonly employed treatment modalities used for traumatic corneal abrasions, i.e. patching, ointment and bandage contact lenses.

With respect to our primary outcome measure (corneal abrasion area reduction), none of the therapeutic options tested were proven to be advantageous. The recently published meta-analysis from Turner and Rabiu [4] found a significantly faster healing time in the groups without patch (compared to with patch) in the treatment of simple corneal abrasions. When they excluded two quasi-randomized studies, the results concurred with our findings. The average abrasion area in our study was 3.8 ± 3.5 mm^2 with a high homogeneity in all three groups as opposed to average areas ranging from 1.6 to 23.7 mm^2 in the studies used for comparison in the aforementioned review [4]. Since our trial was not designed to study very large abrasions or recurrent erosions, the results and recommendations reported here cannot be thoroughly applied for such cases.

A further important parameter for the evaluation of the efficacy of treatment options for corneal abrasions is the amount of pain relief achieved by therapy.

Since the main argument of applying a bandage contact lens is immediate pain relief with almost no impairment in visual acuity, we set out to analyze the amount of pain relief after the short period of 3 h after removal of the foreign body. However, we could not find any statistically significant difference between the three treatment groups concerning this secondary outcome measure. Between-group comparison did remain without statistical significance. Many prior studies investigating this topic have tried to assess pain scores. However, such studies have had similar difficulties reaching statistically significant levels, some even with opposite results [12]. The study of Arbour et al. [14] reported a greater pain reduction in patients treated by patching as opposed to those who had received no patch treatment. However, they stated that 48% of their patients had identified the patch itself as the main source of discomfort.

Subjective pain intensity has been widely studied in the field of oncology and postoperative care and can be measured by visual analog scales and numerical and verbal rating scales [26, 27]. One of the major drawbacks of such tools is the high individual variability with the potential of biased assessment and low reproducibility [24, 28–30], such that it is not surprising to find conflicting results in studies assessing the pain due to corneal abrasions.

All further secondary measures assessed (medical leave, residual corneal opacity and use of oral analgesics) were not significantly different between the treatment groups. In our study all treatment modalities proved to be safe for the patients since no adverse events were diagnosed and the visual acuity was not affected negatively by the therapy. Antibiotic prophylaxis was given for all treated subjects to avoid postinterventional bacterial keratitis. Conjunctival injection was noted to be slightly increased in the CLG and mildly increased in the OG, though this did not reach statistical significance. A possible cause for increased conjunctival injection could be antibiotic toxicity and/or its base (adeps lanae is used for the ointment).

The number of patients allocated to the three groups showed differences due to the termination of study subject recruitment as soon as the minimum group size to achieve the predefined power was reached. We performed the power analysis again after completion of our study. The measured differences in the primary outcome measure detected in our study would necessitate an estimated sample size per group of n = 361 patients to find a statistically significant difference. However, the costs and time to perform such a study would exceed the scientific and clinical relevance by far.

In conclusion, treating traumatic corneal abrasions by pressure patching, a bandage contact lens or ointment alone was equal in terms of reducing the abrasion area and reducing pain. Given these findings, the decision on how to treat can be guided entirely by secondary factors such as personal preferences of the patient, presumed compliance or economic issues. We believe that such a result is of significant practical value since it gives the treating physician complete liberty to choose the option best suited for each individual patient.

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